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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,183	11/10/2003	Stephen D. Hurst	DX01088KB	4790

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EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/705,183	HURST ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *15-27* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's preliminary amendment filed on 10 November 2003 is acknowledged and entered. Following the amendment, the original claims 1-14 are canceled, and the new claims 15-27 are added.

Currently, claims 15-27 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 15-17, drawn to a method of treating an autoimmune condition with an IL-174 agonist, wherein the IL-174 agonist comprises the polypeptide of SEQ ID NO:2, classified in class 424, subclass 85.2.

II. Claims 15, 16 and 18, drawn to a method of treating an autoimmune condition with an IL-174 agonist, wherein the IL-174 agonist comprises an adenoviral construct, classified in class 514, subclass 44.

III. Claims 19-21, drawn to a method of treating a TH-1-mediated condition with an IL-174 agonist, wherein the IL-174 agonist comprises the polypeptide of SEQ ID NO:2, classified in class 424, subclass 85.2.

IV. Claim 22 in part, drawn to a method of stimulating an innate immune response with an IL-174 agonist, classification depending upon the chemical entity of the IL-174 agonist.

V. Claim 22 in part, drawn to a method of augmenting an inflammatory response from epithelial or fibroblast with an IL-174 agonist, classification depending upon the chemical entity of the IL-174 agonist.

VI. Claim 22 in part, drawn to a method of promoting extra medulary hematopoiesis with an IL-174 agonist, classification depending upon the chemical entity of the IL-174 agonist.

VII. Claim 22 in part, drawn to a method of augmenting antibody response in serum and fecal matter with an IL-174 agonist, classification depending upon the chemical entity of the IL-174 agonist.

VIII. Claim 22 in part, drawn to a method of treating an infectious disease with an IL-174 agonist, classification depending upon the chemical entity of the IL-174 agonist.

IX. Claim 22 in part, drawn to a method of treating a wound healing response with an IL-174 agonist, classification depending upon the chemical entity of the IL-174 agonist.

X. Claim 23 in part, and claim 24-26, drawn to a method of preventing mammalian granuloma formation with an IL-174 antagonist, wherein the antagonist is an antibody to the polypeptide of SEQ ID NO:2, classified in class 424, subclass 139.1.

XI. Claim 23 in part, and claim 24-26, drawn to a method of treating a TH2-mediated condition with an IL-174 antagonist, wherein the antagonist is an antibody to the polypeptide of SEQ ID NO:2, classified in class 424, subclass 139.1.

XII. Claim 23 in part, and claim 24-26, drawn to a method of directing immune response away from a TH2-type response with an IL-174 antagonist, wherein the antagonist is an antibody to the polypeptide of SEQ ID NO:2, classified in class 424, subclass 139.1.

XIII. Claim 23 in part, and claim 24-26, drawn to a method of blocking eosinophil attraction, tissue remodeling or fibrosis with an IL-174 antagonist, wherein the antagonist is an antibody to the polypeptide of SEQ ID NO:2, classified in class 424, subclass 139.1.

XIV. Claim 27, drawn to a method of treating an allergic condition with an IL-174 antagonist, wherein the antagonist is an anti-sense nucleic acid, classified in class 514, subclass 44.

The inventions are distinct, each from the other because:

Invention I is distinct from and unrelated to invention II, wherein Invention I is drawn to a method of protein therapy, whereas Invention II is drawn to a method of gene therapy. The

active ingredient in each method is distinct from the other, and cannot be used in the other method. Therefore, non-coextensive searches are required.

Inventions I and III-IX are distinct, each from each other even though they all involve the use of an IL-174 agonist because they are directed to different clinical conditions, which have distinct pathology, clinical manifestations, treatment and prognosis, thus, non-coextensive search is needed for each condition of the methods. Additionally, different active ingredients may involve in these methods, for example, inventions I and III apply the polypeptide of SEQ ID NO:2, whereas inventions IV-IX involve "an IL-174 agonist". Therefore, non-coextensive searches are required.

Invention I is distinct from and unrelated to Inventions X-XIV because Invention I is drawn to a method of treatment using an IL-174 *agonist*, whereas Inventions X-XIV are drawn to a method of treatment using an IL-174 *antagonist*. The active ingredient in Invention I is distinct from that of Inventions X-XIV, and cannot be used in the other methods. Therefore, it would require non-coextensive searches.

Invention II is distinct from and unrelated to inventions III-IX, wherein Invention II is drawn to a method of gene therapy, whereas inventions III-IX are drawn to a method of protein therapy or other IL-174 agonists. Thus, the active ingredient used in Invention II is distinct from that used in the methods of inventions III-IX, and cannot be used in those methods. Additionally, they are directed to methods of treating different conditions. Therefore, non-coextensive searches would be required.

Inventions II-IX are distinct from and unrelated to Inventions X-XIV because Inventions II-IX are drawn to a method of treatment using an IL-174 *agonist*, whereas Inventions X-XIV are drawn to a method of treatment using an IL-174 *antagonist*. Thus, the active ingredients in Inventions II-IX are distinct from that of Inventions X-XIV, and cannot be used in the methods of Inventions X-XIV. Therefore, non-coextensive searches are required.

Inventions X-XIV are distinct, each from each other even though they all involve the use of an IL-174 antagonist because they are directed to different clinical conditions, which have distinct pathology, clinical manifestations, treatment and prognosis, thus, non-coextensive search is needed for each condition of the methods. Additionally, different active ingredients are

involved in these methods, for example, antibody is used in inventions X-XIII, whereas an anti-sense nucleic acid is used in Invention XIV. Therefore, non-coextensive searches are required.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matters, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Species Election

If applicants elect any one of groups I-III and X-XIII, a further election of species is required:

This application contains claims directed to the following patentably distinct species of the claimed invention:

A. If invention I or II is elected:

There are 5 different autoimmune conditions recited in claim 16, and they are: MS, SLE, RA, diabetes and psoriasis.

B. If invention III is elected:

There are 5 different TH-1-mediated conditions recited in claim 21, and they are: Crohn's disease, ulcerative colitis, pancreatitis, hepatitis and eosinophilic gastritis.

C. If any one of inventions X-XIII is elected:

There are 4 different conditions recited in claim 24, and they are: the eosinophils are attracted to the liver or intestine; the fibrosis is pancreatic duct or peribiliary fibrosis; suppressing production of IL-4, IL-5, and/or IL-13; and dermatitis.

The species set forth in A-C above are independent or distinct because:

Each listed condition has different causes, distinct pathological and clinical manifestations, and distinct features in progress and prognosis from the others, and involve distinct patient populations and different therapy, thus, each requires a separate search of the prior art.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 15 and 19 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Advisory Information

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Dong Jiang

Dong Jiang, Ph.D.
Patent Examiner
AU1646
6/16/06